EXHIBIT A

CONFIDENTIAL

SETTLEMENT AND LICENSE AGREEMENT

This is an agreement (hereinafter referred to as "<u>Agreement</u>") dated as of this 21st day of March, 2007 (the "<u>Effective Date</u>"), by and between Adams Respiratory Therapeutics, Inc., Adams Respiratory Operations, Inc. and Adams Respiratory Products, Inc., each such corporation organized and existing under the laws of Delaware (together "<u>Adams</u>"), and Pharmaceutical Holdings Corp., a corporation organized and existing under the laws of Delaware, and Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc., each such corporation organized and existing under the laws of Pennsylvania (together "<u>Mutual</u>"). Adams and Mutual are sometimes individually referred to herein as a "<u>Party</u>" and collectively referred to herein as the "Parties".

WHEREAS, Adams and Mutual are parties to the patent litigations captioned, Adams Respiratory Operations, Inc. v. Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co, Inc. and United Research Laboratories, Inc., Civil Action No. 2:06-CV-04418-PD, and Adams Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co, Inc. and United Research Laboratories, Inc., Civil Action No. 2:06-CV-05485-PD, both of which are pending before the Honorable Paul S. Diamond in the United States District Court for the Eastern District of Pennsylvania ("District Court") and to the related antitrust litigation captioned, Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc. v. Adams Respiratory Operations, Inc., Civil Action No. 2:07-CV-00217-PD, also pending before the Honorable Paul S. Diamond in the District Court (the "Lawsuits"):

WHEREAS, Adams manufactures, markets and sells the pharmaceutical formulations containing 600 and 1200 mg of guaifenesin alone and in combination with other active ingredients under the brand names Mucinex® (guaifenesin 600 mg ER tablets), Mucinex® DM (guaifenesin 600 mg/pseudoephedrine 60 mg ER tablets), Mucinex® D (guaifenesin 600 mg/dextromethorphan 30 mg ER tablets) and Humibid® (guaifenesin 1200 mg ER tablets) and plans to manufacture, market and sell future extended-release products containing guaifenesin (collectively "Adams Guaifenesin Products");

WHEREAS, Mutual filed Abbreviated New Drug Application No. 78-333 (the "<u>Mutual ANDA</u>") seeking permission to market a 600 mg version of Mucinex[®] and a 1200 mg version of Humibid[®];

WHEREAS, Mutual is in the process of developing versions of Mucinex® D and Mucinex® DM;

WHEREAS, the Mutual ANDA contains Paragraph IV Certifications with respect to versions of the Mucinex[®] (guaifenesin 600mg ER tablets) and Humibid[®] (guaifenesin 1200 mg ER tablets) Adams Guaifenesin Products where guaifenesin is the sole active ingredient;

WHEREAS, Adams asserts that Mutual's versions of Mucinex[®] and Humibid[®] infringe Adams' U.S. Patent No. 6,372,252 (the "Adams Patent");

WHEREAS, with respect to the Adams Patent, Mutual has asserted affirmative defenses and counterclaims alleging invalidity, unenforceability and/or non-infringement;

WHEREAS, Mutual admits that the Mutual ANDA and the versions of Mucinex® and Humibid® set forth therein infringe claims 24-28, 31-34 and 40 of the Adams Patent and claims 62-63 from Reexamination 90/007,514 filed April 22, 2005, and that the making, using, selling, offering for sale or importing of the formulation set forth in the Mutual ANDA in versions of Mucinex® D and Mucinex® DM (such as the Mutual Combination Guaifenesin Products defined below) and other guaifenesin products would infringe the Adams Patent;

WHEREAS, Mutual admits that the Adams Patent is valid and enforceable;

WHEREAS, Mutual alleged as claims, counterclaims or affirmative defenses in the Lawsuits that Adams has committed exclusionary, anticompetitive and unlawful acts in violation of the Sherman Act, the Clayton Act and state common law in connection with the Adams Patent and NDA No. 21-282;

WHEREAS, Mutual hereby admits that Adams has not committed any exclusionary, anticompetitive or unlawful act in violation of the Sherman Act, the Clayton Act and/or any state common law in connection with the Adams Patent or NDA No. 21-282 or the Lawsuits;

WHEREAS, Mutual asserted that Adams committed tortious interference and common law unfair competition;

WHEREAS, Mutual admits that Adams has not committed tortious interference or common law unfair competition;

WHEREAS, Mutual agrees to withdraw each of its claims and counterclaims;

WHEREAS, the Parties wish to fully settle the Lawsuits, upon the terms and subject to the conditions set forth in this Agreement;

WHEREAS, this Agreement and the Consent Judgment and Dismissal Without Prejudice (attached hereto as Appendix B) are the only consideration exchanged by or on behalf of Mutual on the one side, and Adams on the other side, in reaching the agreement to dismiss the Lawsuits; and Mutual and Adams have each received no consideration from the other Party for their entry into this Agreement other than that which is described in this Agreement and the Consent Dismissal Without Prejudice; and this Agreement constitutes Mutual's best independent judgment as to how to most expeditiously and competitively sell guaifenesin products in the United States;

WHEREAS, as a result of this Agreement, almost eight (8) years prior to expiration of the Adams Patent, Mutual will have the opportunity to sell a guaifenesin product resulting in

increased competition for Adams Guaifenesin Products, which competition otherwise might not have existed until the expiration of the Adams Patent;

WHEREAS, settlement of the Lawsuits will help both Adams and Mutual avoid the substantial uncertainty and risk involved in prolonged litigation;

WHEREAS, to the extent Mutual seeks approval of formulations subject to this Agreement as Licensed Products, settlement of the Lawsuits will enable Mutual to file future ANDAs seeking final FDA approval of such Licensed Products prior to the expiration of the Adams Patent without being subject to the applicability of an automatic thirty (30)-month stay of FDA approval, which would arise by reason of potential patent actions filed by Adams;

WHEREAS, settlement of the Lawsuits will permit both Adams and Mutual to save litigation costs, as well as to adhere to the judicially recognized mandate that encourages the settlement of litigation;

WHEREAS, as a result of this Agreement, Mutual's ability to enter into competition with the Adams Guaifenesin Products is not subject to its ability to obtain approval of the Mutual products;

WHEREAS, settlement of the Lawsuits will permit the management of both Adams and Mutual to focus their efforts on the conduct of their respective businesses rather than devoting substantial time and resources to litigation;

WHEREAS, the public will benefit significantly from this final settlement as it will save judicial resources and create certainty for Adams and Mutual that will encourage the development, investment and marketing of Mucinex[®], Humibid[®] and other pharmaceutical products;

WHEREAS, money saved by settling the Lawsuits can now be invested by Adams and Mutual into research and development, thereby benefiting consumers by identifying new uses for current drugs, as well as furthering the creation of new medications.

NOW THEREFORE, in consideration of the promises, representations, warranties, covenants and agreements contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby agree as follows:

- 1. The following terms, when used with initial capital letters, shall have the meaning set forth below.
 - a. "Adams Patent" shall mean U.S. Patent No. 6,372,252.
 - b. "Affiliate" shall mean with respect to a Party, any person or entity that controls, is controlled by, or is under common control with, such Party. As used in this definition, "control" means (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or

shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity.

- c. "ANDA" shall mean an Abbreviated New Drug Application filed with the FDA in the Territory as defined in 21 USC § 355(j) and 21 US CFR Part 314.
- d. "Bilayered Products" shall mean for purposes of this Agreement: any (i) guaifenesin-containing tablet comprising two portions compressed against one another so that the face of each portion is exposed as either the top or bottom of the tablet, wherein one portion comprises a sustained-release formulation of guaifenesin and the other portion comprises an immediate-release formulation of guaifenesin; (ii) guaifenesin-containing tablet comprising a core and a coating, wherein the core comprises a sustained-release formulation of guaifenesin in the center of the tablet and the coating comprises an immediaterelease formulation of guaifenesin completely covering the core; or (iii) capsule product comprising beads of an immediate-release formulation of guaifenesin and beads of a sustained-release formulation of guaifenesin. For the sake of clarity, this definition shall not include (without limitation); (v) the formulation set forth in the Mutual ANDA; (w) a formulation only containing a sustained-release formulation as set forth in Col. 3, lines 25-43 of the Adams Patent; (x) any formulation in which essentially all of the guaifenesin is mixed into a single batch or essentially identical batches of excipients; (y) any formulation in which essentially all of the guaifenesin is mixed into one or more batches of excipients comprising a sustained-release polymer; or (z) any formulation that does not contain two separate, discrete and internally contiguous regions of guaifenesin.
- e. "<u>Business Day</u>" shall mean any day other than a Saturday, Sunday or day on which banks in New York, New York are authorized or obligated by applicable law to close. Any reference in this Agreement to "day" whether or not capitalized shall refer to a calendar day, not a Business Day.
- f. "FDA" means the United States Food and Drug Administration and any successor agency having substantially the same functions.
- g. "<u>First Commercial Sale</u>" shall mean the first commercial sale in the Territory of an Adams Guaifenesin Product by Mutual, its Affiliate or single Sublicensee to the Retail Trade. First Commercial Sale shall not include a sale of an Adams Guaifenesin Product among Mutual, a Mutual Affiliate or Mutual's Sublicensee.
- h. "Fully Allocated Cost Basis" shall mean, with respect to a particular Adams Guaifenesin Product in any period, (i) to the extent that such Adams

Guaifenesin Product is manufactured by Adams, the direct costs to Adams of manufacturing the units of finished Adams Guaifenesin Product sold to Mutual during such period as calculated in accordance with generally accepted accounting principles in the United States consistently applied by Adams, including (v) to the extent not already included in clause (w) below, the direct acquisition cost of all raw materials and components, including the active pharmaceutical ingredient used therein, (w) the direct costs, including direct labor and materials, of producing, packaging and labeling such Adams Guaifenesin Product, (x) the direct costs for transportation, insurance and/or storage consistent with the delivery terms of such Adams Guaifenesin Product and any applicable sales taxes, (y) a reasonable allocation of manufacturing overhead costs reasonably attributable to such Adams Guaifenesin Product (but excluding corporate administrative overhead, depreciation and/or costs associated with excess capacity), and (z) any royalty payments made by Adams to Third Parties as consideration for a license to manufacture such Adams Guaifenesin Product); and (ii) to the extent that such Adams Guaifenesin Product is manufactured by a Third Party contract manufacturer, the actual price paid by Adams to such Third Party for the production, packaging and labeling of the units of such Adams Guaifenesin Product sold in such period.

- i. "Gross Profit" shall mean, with respect to an Adams Guaifenesin Product in any period, the aggregate Net Sales of such Adams Guaifenesin Product in such period, less the aggregate Fully Allocated Cost Basis of such Adams Guaifenesin Product in such period.
- j. "<u>IRI Sales</u>" shall mean, with respect to a product in any period, the sales of such product on a pro-rata daily basis in such period as reported by Information Resources, Inc. ("IRI"), or such other sales data source as the Parties may agree in writing.
- k. "Launch Date" has the meaning given such term in Section 5(b)(i).
- 1. "License" has the meaning given such term in Section 4.
- m. "<u>Licensed Patents</u>" shall mean the (i) the Adams Patent and U.S. Patent Application No. 09/559,542 filed April 28, 2000, and any claims that issue from the Reexamination, and (ii) any U.S. reissue, reexamination, continuation, divisional or continuation-in-part thereof.
- n. "Licensed Products" shall mean the collective reference to (i) the Mutual 600 mg Guaifenesin Product, (ii) the Mutual 1200 mg Guaifenesin Product, and (ii) the Mutual Combination Guaifenesin Products, defined herein, as well as (iv) any other product containing guaifenesin that is made with the formulation set forth in the Mutual ANDA; and a "Licensed Product" shall mean each of them.

- o. "Losses" shall mean all pending and potential claims, demands, all manner of actions, causes of action, suits, debts, liabilities, losses, damages, attorneys' fees, costs, expenses, judgments, settlements, interest, punitive damages and other damages or costs of whatever nature, whether known or unknown, pending or future, certain or contingent.
- p. "Marketing License Effective Date" has the meaning given such term in Section 5.
- q. "Mutual 600 mg Guaifenesin Product" shall mean (i) a formulation as defined in the Mutual ANDA containing a total of 600 mg of guaifenesin as its sole active ingredient, (ii) any similar formulation that does not require a new bioequivalence clinical study for FDA approval, or (iii) or any formulation for which Mutual provides Adams with a certification letter pursuant to 21 U.S.C. § 355(j)(2)(B) representing that said formulation is subject to this Agreement as a Licensed Product, but excluding in each case any Bilayered Products.
- r. "Mutual 1200 mg Guaifenesin Product" shall mean (i) a formulation as defined in the Mutual ANDA containing a total of 1200 mg of guaifenesin as its sole active ingredient, (ii) any similar formulation that does not require a new bioequivalence clinical study for FDA approval, or (iii) any formulation for which Mutual provides Adams with a certification letter pursuant to 21 U.S.C. § 355(j)(2)(B) representing that said formulation is subject to this Agreement as a Licensed Product, but excluding in each case any Bilayered Products.
- s. "<u>Mutual ANDA</u>" shall mean the Abbreviated New Drug Application No. 78-333.
- t. "Mutual Combination Guaifenesin Products" shall mean the collective reference to: (i) Mutual's combination formulation containing 60 mg or 120 mg of pseudoephedrine and a Mutual 600 mg Guaifenesin Product, (ii) Mutual's combination formulation containing 30 mg of dextromethorphan and a Mutual 600 mg Guaifenesin Product, or (iii) any formulation for which Mutual provides Adams with a certification letter pursuant to 21 U.S.C. § 355(j)(2)(B) representing that said formulation is subject to this Agreement as a Licensed Product, but excluding in each case Bilayered Products.
- u. "Net Sales" shall mean, with respect to an Adams Guaifenesin Product in any period, the gross sales revenue for such Adams Guaifenesin Product actually invoiced by Adams or its Affiliates or by Mutual, its Affiliates or its single Sublicensee, as the case may be, to the Retail Trade in the Territory, less (i) trade, quantity and early pay cash discounts or rebates which are actually deducted, (ii) amounts repaid or credited by reason of returns and rebates, including any statutory or contractual liability for rebates to be paid to or for

the benefit of any government entity including, but not limited to, rebates to be paid pursuant to federal, state and local government rebate legislation and/or programs, (iii) any adjustments granted to customers for repayments, allowances or credits for rejected Adams Guaifenesin Product, retroactive price adjustements (e.g., floorstock adjustments), reprocurement fees, damaged Adams Guaifenesin Product, promotional allowances, chargebacks, disputed amounts (that are actually not paid and written off by Adams or Mutual, as the case may be), or other customary discounts, deductions and administrative fees, (iv) special handling fees, transportation and insurance charges to the extent included in the invoice price, or (v) actual sales, use or excise taxes, tariff or customs duties, and other governmental charges to the extent included in the invoice.

- v. "Notice Date" has the meaning given such term in Section 5(b).
- w. "Paragraph IV Certification" shall mean a certification as defined in 21 U.S.C. 355(j)(2)(A)(vii)(IV).
- x. "<u>Person</u>" or "<u>Persons</u>" shall mean any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental authority, or other entity or organization.
- y. "<u>Proceeding</u>" shall mean any action, audit, litigation, investigation, suit or other proceeding.
- z. "Reexamination" shall mean Reexamination 90/007,514 filed April 22, 2005, claims 62-63 of which are attached hereto as Appendix A.
- aa. "Related Party" has the meaning given such term in Section 2.
- bb. "<u>Retail Trade</u>" shall mean a Third Party that will sell a Licensed Product directly to the public ("<u>Retailer</u>"), and any distributors of such Licensed Product to the retail trade that do not package or repackage such Licensed Product and that do not sell such Licensed Product to any entity other than a Retailer.
- cc. "<u>Sublicensee</u>" shall mean a person or entity to whom Mutual grants a single sublicense pursuant to Section 4.
- dd. "Supply Agreement" has the meaning given such term in Section 6.
- ee. "<u>Territory</u>" shall mean the United States of America and its territories, commonwealths and possessions, including without limitation the Commonwealth of Puerto Rico and the District of Columbia.

- ff. "Third Party" shall mean any person or entity other than Adams and Mutual or their respective Affiliates.
- gg. "Third Party Launch Notice" has the meaning given such term in Section 5(b).
- hh. "Third Party Formulation" shall mean an extended-release pharmaceutical formulation, other than the Licensed Products, that is bioequivalent to an Adams Guaifenesin Product or bioequivalent to any other Adams' product containing guaifenesin.
- Upon the terms and subject to the conditions of this Agreement, in consideration of the mutual execution of this Agreement and the mutual agreement to be legally bound by the terms hereof, each Party, on behalf of itself and its Affiliates, directors, officers, employees. agents, representatives, heirs, assigns, predecessors or successors ("Related Parties"), hereby releases, acquits and forever discharges the other Party and its Related Parties from any and all Losses arising out of, derived from, predicated upon or relating to the infringement of the Adams Patent or the Reexamination by the Licensed Products, or the actions underlying the Lawsuits; provided, however, that nothing in this Agreement shall prevent or impair the right of either Party to bring a Proceeding in state or federal courts located in the Eastern District of Pennsylvania for a breach of this Agreement (including, without limitation, any claim for infringement of any intellectual property based upon activities that are not the subject of the license grants hereunder) or any representation, warranty or covenant herein or therein. The Parties agree to the entry of a Consent Dismissal Without Prejudice in the Lawsuits, which provides that each Party shall bear its own costs of suit and attorneys' fees. To effectuate this provision, promptly following the execution of this Agreement, the Parties shall cause the Consent Dismissal Without Prejudice attached hereto as Appendix B (each Party acknowledging that the approval of the Court is required in order to make such Consent Dismissal Without Prejudice effective) to be filed with the District Court, and shall take all other necessary actions to obtain the settlement and dismissal of the Lawsuits.
 - 3. Each Party acknowledges and agrees that:
 - (a) It may have sustained Losses arising out of, derived from, predicated upon or relating to the infringement of the Adams Patent or the Reexamination by the Licensed Products, or the actions underlying the Lawsuits, that are presently unknown and unsuspected, and that such actions might give rise to such Losses in the future. Nevertheless, each Party acknowledges and agrees that this Agreement has been negotiated and agreed upon, notwithstanding the existence of such possible Losses, all of which have been hereby released under Section 2 hereof.
 - (b) If any fact relating to this Agreement or the Lawsuits and now believed to be true is found hereafter to be other than, or different from, that which is now believed, each Party expressly assumes the risk of such difference in fact and agrees that this Agreement shall be, and will remain, effective

- notwithstanding any such difference in fact, subject to each Party's right to bring a Proceeding for a breach of any representation or warranty herein.
- (c) This Agreement may be pleaded as a full and complete defense to, and used as a basis for injunction against, any Proceeding that may be instituted, prosecuted or attempted in breach hereof.
- 4. (a) Adams hereby grants to Mutual a non-exclusive, royalty-free, perpetual and irrevocable license under the Licensed Patents (the "License") to make, have made, sell or offer for sale to the Retail Trade, use and import each Licensed Product commencing on or after the applicable Marketing License Effective Date for such Licensed Product (as defined below in Section 5). For clarity, the License includes, without limitation, the right of Mutual or one of its Affiliates to (i) make, use, import and have made reasonable launch quantities of each Licensed Product up to six (6) months prior to the applicable Marketing License Effective Date, and (ii) sell or offer for sale, but not ship, reasonable launch quantities of each Licensed Product up to one (1) month prior to the applicable Marketing License Effective Date.
- (b) The License includes the right to grant sublicenses under the License to (i) any Related Party for any purpose, and (ii) a single Third Party solely for the purpose of selling or offering for sale to the Retail Trade. If Mutual sublicenses any of its rights under the License with respect to a Licensed Product to a Third Party, Mutual agrees that it and its Affiliates will not sell or offer for sale such Licensed Product. For clarity, only one of Mutual and its Affiliates, on the one hand, or a single Sublicensee, on the other hand, may sell to the Retail Trade pursuant to this paragraph.
- 5. As to each Licensed Product, the "Marketing License Effective Date" shall be defined as follows:
 - (a) Mutual 600 mg Guaifenesin Product: Subject to Section 5(b) below, the Marketing License Effective Date for the Mutual 600 mg Guaifenesin Product shall be the later of (i) July 1, 2012 or (ii) the date Mutual obtains FDA approval to market such Licensed Product.
 - (b) All Licensed Products: Mutual shall provide Adams notice within five (5) business days if it obtains final FDA approval for any Licensed Product. If Mutual has obtained FDA approval of a Licensed Product and has notified Adams of that approval, then Adams shall notify Mutual promptly in writing if it reasonably believes that a particular Third Party likely will commence the lawful sale of a Third Party Formulation corresponding to such Licensed Product in the Territory, and shall include in such notice (a "Third Party Launch Notice") Adams' reasonable, good faith estimate of the first lawful commercial sale of such Third Party Formulation ("Notice Date"). Mutual shall notify Adams in writing if Mutual reasonably believes that a particular Third Party will commence the lawful sale of a particular Third Party Formulation, and shall include in such notice Mutual's reasonable, good faith estimate of such commencement date.

Mutual shall not have the right to set the Notice Date. If Adams, after sending a Third Party Launch Notice, subsequently learns of new information, it may amend such Third Party Launch Notice; provided, however, that Adams may not amend a Third Party Launch Notice to change the Notice Date in such Third Party Launch Notice at any time after the date which is ninety (90) days prior to such Notice Date.

(i) I f Mutual obtains approval from FDA to market a Licensed Product and receives a corresponding Third Party Launch Notice, then the Marketing License Effective Date for such Licensed Product shall be the date that is sixty (60) days prior to the Notice Date in such Third Party Launch Notice; provided, however, that if a Third Party launches a corresponding Third Party Formulation and it and all other Third Parties selling a corresponding Third Party Formulation are subsequently enjoined by a court with appropriate jurisdiction in a final, non-appealable judgment from selling their respective corresponding Third Party Formulations in the Territory, then Mutual shall cease selling such Licensed Product until a Third Party commences or re-commences the lawful sale of a corresponding Third Party Formulation in the Territory.

If the actual date of first lawful commercial sale of a formulation corresponding to the Licensed Product in such Third Party Launch Notice ("Launch Date") by (x) a Third Party or (y) Adams or its Affiliates under a private label, a store brand name or a genericized brand name used for such corresponding Third Party Formulation, then:

- (A) if such Launch Date occurs prior to the Notice Date but *after* the Marketing License Effective Date, then Adams shall pay Mutual an amount equal to ten percent (10%) of the aggregate IRI Sales of Adams, its Affiliates and licensees (other than licensees under this Agreement) of the Adams Guaifenesin Product corresponding to such Licensed Product for each day in which the period between the Marketing License Effective Date and the Launch Date is less than fifty (50) days; provided, however, that if Adams fails to notify Mutual of a Notice Date or Launch Date that Adams knows or in good faith should know is likely to occur, then Adams shall pay Mutual an amount equal to the Gross Profit for such Adams Guaifenesin Product in such period; or
- (B) if such Launch Date occurs prior to the Notice Date but *before* the Marketing License Effective Date or if such Launch Date occurs and Adams has not notified Mutual of a Notice Date (in which case such Launch Date shall be deemed the Marketing License Effective Date), Adams shall pay Mutual an amount equal to ten percent (10%) of the aggregate IRI Sales of Adams, its Affiliates and licensees (other than licensees under this Agreement) of the Adams Guaifenesin Product corresponding to such Licensed Product for each day in which Mutual's launch of its corresponding

Licensed Product is delayed beyond the day that is fifty (50) days prior to such Launch Date, said period not to exceed one hundred twenty (120) days in total; provided, however, that if Adams fails to notifies Mutual of a Notice Date or Launch Date that Adams knows or in good faith should know is likely to occur, then Adams shall pay Mutual an amount equal to Adams' Gross Profit for such Adams Guaifenesin Product in such period; or

(C) if such Launch Date occurs after the Notice Date, then Mutual shall pay Adams an amount equal to ten percent (10%) of the aggregate IRI Sales of Mutual, its Affiliates and its Sublicensee of such Licensed Product during the period commencing seventy (70) days after the Marketing License Effective Date through such Launch Date. Mutual's IRI Sales shall be calculated starting from the date of the first report by IRI of sales more than \$25,000, for a period of the time equaling the number of days between 70 days after the Marketing License Effective Date and the Launch Date. Mutual agrees to provide all required account information necessary to track Mutual's IRI data.

Payments from Adams to Mutual under this Section 5(b)(i) shall be due within sixty (60) days after the end of the applicable payment calculation period described in clause (A) or (B) above, as applicable, together with a written report containing information in sufficient detail to permit confirmation of the accuracy of the payment made. Payments from Mutual to Adams described in clause (C) above shall be made quarterly as set forth in Section 6(c).

Neither Party shall be entitled to any other money damages resulting from a Launch Date failing to occur on the Notice Date or failure to provide a Notice Date, however, this liquidated damages provision shall not affect the availability of any equitable relief to which either Party might otherwise be entitled.

(ii) If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation or Adams Guaifenesin Product, then the Marketing License Effective Date shall be the date on which Mutual obtains FDA approval to market such Licensed Product corresponding to such FDA-approved Third Party Formulation. Mutual, in its sole discretion, may purchase from Adams and Adams shall supply, pursuant to the terms of Section 6 of this Agreement, tablets of the Adams Guaifenesin Product corresponding to such Third Party Formulation, for sale by Mutual, its Affiliates or a single independent Sublicensee to the Retail Trade under a private label or a brand name other than Adams' brand names for the Adams Guaifenesin Product, in the Territory commencing no earlier than ninety (90) days after the corresponding Launch Date. To the extent that Mutual purchases tablets of Adams Guaifenesin Product pursuant to the Supply Agreement, Adams grants Mutual a nonexclusive, perpetual and irrevocable right to sell and offer for sale to the Retail Trade such tablets supplied by Adams under the Licensed Patents in the

Territory and agrees, in a timely manner, to take all steps with respect to the New Drug Applications and/or other marketing authorizations for such Adams Guaifenesin Product that are necessary in order to manufacture and supply such Adams Guaifeneisin Product tablets to Mutual hereunder and under the Supply Agreement and to ensure that Mutual and its Affiliates or its single Sublicensee, as the case may be, is authorized to sell such Adams Guaifenesin Product. Only Mutual and its Affiliates, on the one hand, or a single Sublicensee, on the other hand, may sell to the Retail Trade pursuant to this paragraph.

- 6. (a) Mutual shall notify Adams in writing of its election to purchase tablets of Adams Guaifenesin Product pursuant to Section 5(b)(ii), and the Parties shall promptly execute a supply agreement in the form attached hereto as Appendix C ("Supply Agreement"). The tablets supplied by Adams shall be white and/or in such other reasonable mono-colored configuration mutually agreeable to the Parties, and shall be manufactured using Adams' and its Affiliates' bilayered technology.
- (b) In consideration for such supply, Mutual shall pay Adams a supply price equal to the sum of the Fully Allocated Cost Basis for such tablets, and a royalty of ten percent (10%) of the Net Sales of Mutual, its Affiliates or its Sublicensee of such Adams Guaifenesin Product in the Territory. Only one royalty shall be due with respect to the same unit of Adams Guaifenesin Product. No royalties shall be due upon the sale or other transfer among Mutual, its Affiliates and a single Sublicensee, but in such cases the royalty shall be due and calculated upon such Net Sales to the first independent Third Party in the Retail Trade.
- (c) Within sixty (60) days after the end of each calendar quarter after the First Commercial Sale of an Adams Guaifenesin Product by Mutual, Mutual shall deliver to Adams a written report containing the following information for the prior calendar quarter, in sufficient detail to permit confirmation of the accuracy of the royalty payment made: (i) the gross sales invoiced for such Adams Guaifenesin Product by Mutual and its Affiliates or its single Sublicensee, (ii) a calculation of Net Sales of such Adams Guaifenesin Product that is sold by Mutual, its Affiliates and its single Sublicensee; (iii) the amount of taxes, if any, withheld to comply with applicable law; and (iv) a calculation of payments due to Adams with respect to the foregoing. Concurrent with these reports, Mutual shall remit to Adams any payment due for the applicable calendar quarter. All such reports shall be considered Confidential Information of Mutual and shall be maintained in confidence by Adams pursuant to Section 20.
- (d) If Mutual concludes that tax withholdings under the applicable law are required with respect to payments to Adams, Mutual shall withhold the required amount and pay it to the appropriate governmental authority.
- (e) All dollar (\$) amounts specified in this Agreement are United States dollar amounts and all payments to be made under this Agreement shall be made in United States dollars and shall be paid by bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by the receiving Party from time to time.

- Mutual and its single Sublicensee (as applicable) shall keep correct and complete books of accounts and other records containing all information and data which may be necessary to ascertain and verify the royalties and other amounts payable by Mutual to Adams under Sections 5(b)(i) and 6(b) of this Agreement. Adams shall keep correct and complete books of accounts and other records containing all information and data which may be necessary to ascertain and verify the amounts payable by Adams to Mutual under Section 5(b)(i) of this Agreement. During the term of this Agreement and for a period of two (2) years following its termination or expiration, each Party (the "Payee") shall have the right from time to time (at its expense) to have an independent certified public accountant inspect such books and records of the other Party (the "Payor"), its Affiliates, and its single Sublicensee (if applicable). Such inspection shall be conducted after reasonable prior notice by the Payee to the Payor during the Payor's ordinary business hours and shall not be more frequent than once during each calendar year. Any such independent certified accountant shall be reasonably acceptable to the Payor, shall execute the Payor's standard form of confidentiality agreement, and shall be permitted to share with the Payee solely its findings with respect to the accuracy of the royalties or other amounts reported as payable under this Agreement. If such accounting determines that the Payor paid the Payee less than the amount properly due in respect of any period, then the Payor shall promptly reimburse the Payee such amount and if the amount underpaid exceeds five percent (5%) of the amount actually due then the Payor shall also reimburse the Payee for the costs of such audit.
- (g) The Payor shall pay interest to the Payee on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of one percent (1%) per month or the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due and compounded monthly.
- 7. Mutual hereby admits that the products described in the Mutual ANDA would infringe claims 24-28, 31-34 and 40 of the Adams Patent and claims 62-63 (Appendix A) from the Reexamination in the Territory, and that if Mutual were to make, use, offer for sale, or sell a Licensed Product in the Territory, such product would infringe said claims of the Adams Patent and the Reexamination, respectively. Notwithstanding the above, nothing in this Agreement shall be construed or cited as an admission of infringement (a) by any product other than a Licensed Product or (b) of any foreign patent or currently pending patent applications.
- 8. Mutual hereby admits that the Adams Patent and claims issuing from the Reexamination are valid and enforceable in the Territory and agrees not to challenge the validity or enforceability of the Adams Patent in the Territory on any grounds in the future. Notwithstanding the above, nothing in this Agreement shall (a) be construed or cited as an admission of validity or enforceability of any foreign patent or currently pending patent applications or (b) prohibit Mutual from asserting that a non-Licensed Product does not infringe the Adams Patent or claims issuing from the Reexamination on the grounds that such non-Licensed Product is identical to prior art not currently known to Mutual and/or its counsel. Prior art currently known to Mutual and/or its counsel includes, but is not limited to, all prior art cited: (i) in the Lawsuit, (ii) in the Adams patent, (iii) in the Reexamination, (iv) in U.S. Patent

No. 6,955,821 and (v) in any divisional, continuation, or continuation in part of U.S. Application No. 09/559,542 that is currently publicly available, or any other prior art that is currently in the possession of Mutual or its counsel.

- 9. In the event Mutual breaches this Agreement by launching a Licensed Product prior to its Marketing License Effective Date, Mutual hereby consents to the entry of a preliminary injunction prohibiting such sales.
- 10. If Mutual files a new ANDA and provides a certification letter pursuant to 21 U.S.C. § 355(j)(2)(B) representing that the new formulation is a Licensed Product, then all references in this Agreement to the Mutual ANDA shall automatically include such new ANDA. Nevertheless, nothing in this Agreement shall prohibit Adams from commencing a patent infringement suit against Mutual based upon a new ANDA seeking FDA approval of Bilayered Products.
- 11. In accordance with 35 U.S.C. § 287, Mutual agrees to affix or provide the proper patent markings to all Licensed Products offered for sale or sold under this Agreement.
- 12. Mutual acknowledges and agrees that, except as otherwise expressly stated in this Agreement, nothing in this Agreement gives Mutual any rights: (a) with respect to any Licensed Product outside the Territory; (b) with respect to any product other than a Licensed Product; or (c) to make, use, import, offer for sale, market or sell any generic version of any Adams guaifenesin product at any time prior to the applicable Marketing License Effective Date.
- FDA's review of Mutual's, Mutual's Affiliates or its single Sublicensee's ANDAs for Licensed Products or to comment on such ANDAs to FDA. To the extent Mutual continues to seek FDA approval of the Mutual ANDA, Mutual hereby confirms its prior statement to FDA that it intends to submit to FDA's Office of Generic Drugs all bioequivalence data that Mutual submitted in NDA 21-950 and all correspondence between FDA and Mutual regarding NDA 21-950. If Mutual decides to withdraw its ANDA, Mutual will do so within five (5) days of making that decision. If Mutual decides to pursue approval of the Mutual ANDA or refile the Mutual ANDA, Mutual affirms that it will submit the foregoing biostudies and correspondence to FDA's Office of Generic Drugs in sufficient time to allow review of this information prior to approval of the Mutual ANDA.
- 14. Adams hereby covenants not to sue Mutual for patent infringement for making, using, selling or offering for sale Licensed Products, including without limitation a suit under 35 U.S.C. § 271(e)(2) in response to the filing of an ANDA by Mutual, except if making, using, selling or offering for sale Licensed Products is a violation or breach of the Agreement, Adams may initiate suit against Mutual.
- 15. Each Party hereto represents and warrants to the other Party that, as of the date hereof:

- (a) this Agreement is a legal, valid and binding obligation of the warranting Party, enforceable against such Party in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by general principles of equity;
- (b) the warranting Party is not subject to any judgment, order, injunction, decree or award of any court, administrative agency or governmental body that would or might interfere with its performance of any of its material obligations hereunder; and
- (c) the warranting Party has full power and authority to enter into and perform its obligations under this Agreement in accordance with its terms.
- 16. Adams represents and warrants that, as of the date hereof, it (i) presently owns, licenses or has the legal rights to the Adams Patent and NDA No. 21-282, (ii) has the legal right to grant the License and other rights granted to Mutual hereunder, (iii) has the right to settle the Lawsuits, and (iv) is required to pay a royalty in respect of the manufacture of Adams Guaifenesin Products of not more than \$500,000 dollars annually. Mutual represents and warrants that it has the right to settle the Lawsuits. Mutual further represents and warrants that, as of the date hereof, Mutual Pharmaceutical Company, Inc. presently owns and has the legal rights to the Mutual ANDA.
- 17. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.
- 18. Neither Party hereto may assign any of its rights or obligations under this Agreement without the prior written consent of the other Party, except to an Affiliate, or in connection with a merger, reorganization, change of control or sale of all or substantially all of the business of such Party to which this Agreement relates. Any purported assignment in violation of the foregoing shall be null and void *ab initio* and of no force or effect. No assignment of this Agreement will relieve the assigning Party from any of its obligations hereunder. In the event of a permitted assignment, this Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns.
- 19. For avoidance of doubt, all rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (the "Bankruptcy Code"), licenses of "intellectual property" as defined under the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code; provided, however, that should Adams become a party to a bankruptcy proceeding and such proceeding is not dismissed within thirty (30) days then, to the extent permitted by law, this Agreement and the licenses granted by Adams hereunder shall be adopted by any bankruptcy trustee or relevant Third Party charged with the disposition of same, and shall not be rejected by same, it being the Parties' intent that, in

such event, Mutual and its Affiliates and single Sublicensee shall be entitled to retain the rights granted to them hereunder by Adams.

20.

(a) With respect to the Confidential Information pertaining to the subject matter of this Agreement that was exchanged between the Parties prior to the Effective Date of the Agreement, the Protective Order entered in the Lawsuit shall govern; provided, however, that each Party agrees that within five (5) years after the Effective Date, unless subject to litigation, it shall return to the other Party all documentation or other tangible evidence or embodiment of Confidential Information belonging to the other Party that it or its outside counsel has retained pursuant to the Protective Order and not to use same, unless otherwise agreed in writing. With respect to Confidential Information exchanged after the Effective Date of the Agreement, each Party shall keep confidential and not disclose to others or use for any purpose, other than as authorized by this Agreement or the Supply Agreement, all such Confidential Information that was provided to it by the other Party or its Affiliates or Sublicensee or their respective employees or representatives. For purposes of this Agreement, "Confidential Information" means proprietary or confidential know-how, trade secrets, formulae, data, inventions, technology and other information of such Party. To the extent a Party considers information "Confidential" under this Agreement, it shall be so identified and marked, or if provided orally shall be memorialized in writing and identified as "Confidential" within thirty (30) days after disclosure. This Section shall not apply to any Confidential Information that: (i) was already known to the recipient at the time of disclosure, as reasonably documented by written records; (ii) is or later becomes public knowledge through no fault of the recipient; (iii) is received from a Third Party having the lawful right to disclose the information; or (iv) is independently developed by employees of the recipient without access to the disclosing Party's Confidential Information. A Party may disclose Confidential Information of the other Party to (x) its Affiliates and Sublicensee, and to its and their directors, employees, consultants and agents, in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use, and (y) to the extent such disclosure is required to comply with applicable law or to defend or prosecute litigation; provided, however, that the receiving Party provides prior written notice of such disclosure pursuant to clause (v) to the disclosing Party and takes reasonable an lawful actions to avoid or minimize the degree of such disclosure, including upon the disclosing Party's request, seeking confidential treatment of such Confidential Information. Upon the expiration or termination of this Agreement for any reason, each Party agrees, except as otherwise provided in this Agreement, to return within thirty (30) days to the other Party all documentation or

- other tangible evidence or embodiment of Confidential Information belonging to the other Party and not to use same, unless otherwise agreed in writing.
- (b) Prior to the execution of this Agreement by both Parties the Parties shall agree in writing upon one or more press releases to be issued separately by the Parties publicizing the execution of this Agreement, and any Party holding a press conference regarding this Agreement shall provide a copy of the transcript sufficiently in advance to provide an opportunity for the other Party to provide comments. Each Party agrees that it will not make disparaging public comments about the other Party in connection with this Agreement, the Lawsuits or the Mutual ANDA. Mutual affirms that it does not currently intend to send out a press release publicizing the execution of this Agreement. Except as consistent with press releases mutually agreed by the Parties, and information disclosed in this Agreement as provided to the pertinent regulatory authorities such as the Securities and Exchange Commission, no public announcement or other disclosure to Third Parties concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by either Party. without first obtaining the written approval of the other Party and agreement upon the nature, text and timing of such announcement or disclosure; provided, however, either Party shall have the right to make any such public announcement or other disclosure required by law after such Party has provided to the other Party a copy of such announcement or disclosure and a reasonable opportunity to comment thereon. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure.

21. The Parties each covenant that, at their own expense:

- (a) they shall use their respective reasonable efforts to resolve any and all objections that may be asserted with respect to this Agreement under any applicable law;
- (b) they shall use their respective reasonable efforts to obtain approval of this Agreement under all applicable laws and shall make all required filings with all governmental authorities, including without limitation the reporting of this Agreement to the Federal Trade Commission and the Department of Justice pursuant to Section 1112 of Title XI of the Medicare Prescription Drug Improvement and Modernization Act of 2003;
- (c) they shall use their respective reasonable efforts to comply with and terminate any investigation or inquiry regarding the Agreement by any

- government authority, including in exchanging information, permitting reasonable access to Adams' and Mutual's documents, officials and data in connection with receiving approvals of this Agreement by all governmental authorities;
- (d) if any administrative, judicial or legislative action or proceeding is instituted (or threatened to be instituted) challenging the transaction contemplated by this Agreement as violative of any applicable law, Adams and Mutual will render reasonable assistance to contest and resist any such action or proceeding, and to have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) that is in effect and that challenges this Agreement, including, without limitation, by pursuing all reasonable avenues of administrative and judicial appeal; and
- (e) they shall promptly inform each other of any material communication made to, or received by such Party from any governmental authority regarding this Agreement.
- 22. The relationship between the Parties created by this Agreement is one of independent contractors. Neither Adams nor Mutual shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.
- 23. Should this Agreement be rendered null and void for any reason, Adams agrees not to use any of the stipulations contained herein or attached hereto in any subsequent litigation.
- 24. Any representation, warranty, covenant, term or condition of this Agreement which may legally be waived, may be waived, or the time of performance thereof extended, at any time by the Party hereto entitled to the benefit thereof, and any term, condition or covenant (including, without limitation, the period during which any condition is to be satisfied or any obligation performed) may be amended by the Parties hereto at any time. Any such waiver, extension or amendment by a Party shall be evidenced by an instrument in writing executed by an officer of such Party authorized to execute waivers, extensions or amendments. No waiver by any Party, whether express or implied, of its rights under any provision of this Agreement or otherwise shall constitute a waiver of such Party's rights under any other provision of this Agreement. No failure by any Party to take any action against any breach of this Agreement or default by the other Party shall constitute a waiver of the non-breaching Party's right to enforce any provision of this Agreement or to take action against such breach or default or any subsequent breach or default by such other Party.
- 25. The Parties agree and acknowledge that this Agreement is the product of both Parties and shall not be construed against either of the Parties other than in accordance with its

terms. The Parties acknowledge that each has been advised by counsel during the course of negotiation of this Agreement and, therefore, that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted.

- 26. The Parties agree that there is no adequate remedy at law for the damage which either Party might sustain for breach of this Agreement and, accordingly, each Party shall be entitled, as its option, to specific performance, in addition to any other remedy at law or in equity, to enforce the terms hereof.
- 27. All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be (as elected by the Party giving such notice) hand delivered by messenger or courier service, or mailed by registered or certified mail (postage prepaid), return receipt requested, or delivered by overnight delivery service, addressed to:

In the case of Adams:

Adams Respiratory Therapeutics, Inc. 4 Mill Ridge Lane
Mill Ridge Farm
Chester, NJ 07930
Attention: CEO

with a copy to

Adams Respiratory Therapeutics, Inc. 4 Mill Ridge Lane
Mill Ridge Farm
Chester, NJ 07930
Attention: General Counsel

and

In the case of Mutual:

Mutual Pharmaceutical Company, Inc. 1100 Orthodox Street Philadelphia, PA 19124 Attention: President

with a copy to:

Mutual Pharmaceutical Company, Inc. 1100 Orthodox Street

Philadelphia, PA 19124 Attention: Legal Department

Each such notice shall be deemed delivered (a) on the date delivered if by personal or overnight delivery, and (b) on the date upon which the return receipt is signed or delivery is refused or the notice is designated by the postal authorities as not deliverable, as the case may be, if mailed. A contemporaneous courtesy copy of any communications with FDA under this Agreement shall be provided to a single designated outside law firm, which shall not communicate this information to Adams.

- 28. This Agreement and any dispute arising out of or related to this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York, without giving effect to conflicts of law principles that would dictate the application of the law of another jurisdiction. Any Proceeding against any Party with respect to this Agreement or any judgment entered by any court in respect of this Agreement shall be brought in state or federal courts located in the Eastern District of Pennsylvania, and the Parties hereto accept the exclusive jurisdiction of such courts for the purpose of any such suit, action or proceeding. In addition, the Parties irrevocably waive, to the fullest extent permitted by law, any objection that they may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement, or any judgment entered by any court in respect hereof brought in the Eastern District of Pennsylvania and further irrevocably waive any claim that any suit, action or proceeding brought in the Eastern District of Pennsylvania was brought in an inconvenient forum.
- 29. This Agreement may be executed in any number of counterparts, and execution by each of the Parties of anyone of such counterparts will constitute due execution of this Agreement. Each such counterpart hereof shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement.
- 30. This Agreement, including the Appendices attached hereto, together with the Supply Agreement, contains every obligation and understanding between the Parties relating to the subject hereof and merges all prior discussions, negotiations and agreements, if any, between them, and none of the Parties shall be bound by any conditions, definitions, understandings, warranties or representations other than as expressly provided or referred to herein.
- 31. If any provision of this Agreement is held invalid, illegal or unenforceable for any reason, the Parties shall negotiate in good faith for a substitute provision to continue the intent and purpose of such invalid provision taking into account the intent and purpose of the overall Agreement, and the validity, legality and enforceability of the remaining provisions shall not be in any way impaired thereby.
- 32. No person other than the Parties hereto and their respective Affiliates, successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any legal or equitable rights or benefits to enforce any provision of this Agreement.

This Agreement is signed as indicated below by duly authorized representatives of Adams and Mutual, respectively, effective as of the date first written above.

ADAMS RESPIRATORY THERAPEUTICS, INC.
By: fleshe
Name: Robert O. Casale
Title:
Date: 3/21/2007
ADAMS RESPIRATORY OPERATIONS, INC.
By: Lusale
Name: Robert D. Casale
Title: <u>COO</u>
Date: 3/2//2007
ADAMS RESPIRATORY PRODUCTS, INC.
By: flusale
Name: Robert D. Casale
Title:
Date: 3/21/2007

FRANKACEUTICAL RULDENGS CORF.
By: Lubard Hotela MW
Name: Richard H Roberts, M.D., P
Title: free + CEO
Date: 3/21/07
MUTUAL PHARMACEUTICAL CO., INC.
By: Ridal & Klert MOW
Name: Richard H Roberts, MA, PhD
Title: Pres. + CE
Date: 3/24/07
UNITED RESEARCH LABORATORIES, INC.
By: Rila Vfolia M &
Name: Richard H Roberts, Md, Ob
Title: Prez + CEO
Date: 3/2//07

APPENDIX A

CLAIMS 62 AND 63 OF REEXAMINATION 90/007,514 FILED APRIL 22, 2005

- 62. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a fasted serum guaifenesin concentration profile of Figure 11, wherein the total quantity of guaifenesin is 600 mg, and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.
- 63. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a fasted serum guaifenesin concentration profile of Figure 11, wherein the total quantity of guaifenesin is 1200 mg, and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

APPENDIX B

CONSENT JUDGMENT AND DISMISSAL WITHOUT PREJUDICE

[Consent Judgment appears on the following pages]

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ADAMS RESPIRATORY OPERATIONS, INC.)
Plaintiff,)
v.) C.A. No. 2:06-cv-04418-PD
PHARMACEUTICAL HOLDINGS CORP., MUTUAL PHARMACEUTICAL CO., INC., and UNITED RESEARCH LABORATORIES, INC.)))
Defendants.)
ADAMS RESPIRATORY THERAPEUTICS, INC	
Plaintiff,)
v.) C.A. No. 2:06-cv-05485-PD
PHARMACEUTICAL HOLDINGS CORP., MUTUAL PHARMACEUTICAL CO., INC., and UNITED RESEARCH LABORATORIES, INC.)))
Defendants.) _)

PHARMACEUTICAL HOLDINGS CORP., MUTUAL PHARMACEUTICAL CO., INC., and UNITED RESEARCH LABORATORIES, INC.	
Plaintiffs,) C.A. No. 2:07-cv-00217-PD
v.	
ADAMS RESPIRATORY OPERATIONS, INC.)
Defendants.))

CONSENT JUDGMENT AND DISMISSAL WITHOUT PREJUDICE

Adams Respiratory Operations, Inc. ("ARO") and Adams Respiratory

Therapeutics, Inc. ("ART") (collectively "Adams") and Pharmaceutical Holdings Corp., Mutual

Pharmaceutical Co., Inc. and United Research Laboratories, Inc. (collectively "Mutual")

STIPULATE THAT:

1. Adams and Mutual are parties to the patent litigations captioned Adams
Respiratory Operations, Inc. v. Pharmaceutical Holding Corp., Mutual Pharmaceutical Co., Inc.
and United Research Laboratories, Inc., Civil Action No. 2:06-CV-04418-PD, and Adams
Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co.,
Inc. and United Research Laboratories, Inc., Civil Action No. 2:06-CV-05485-PD, both of
which are pending before the Honorable Paul S. Diamond in the United States District Court for
the Eastern District of Pennsylvania, and are also parties to the related antitrust litigation
captioned Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co., Inc. and United
Research Laboratories, Inc. v. Adams Respiratory Operations, Inc., Civil Action No. 2:07-CV-

00217-PD, also pending before the Honorable Paul S. Diamond in the United States District Court for the Eastern District of Pennsylvania (collectively the "Lawsuits").

- 2. Adams and Mutual wish to settle the Lawsuits.
- This Court has jurisdiction over the parties and the subject matter of the Lawsuits.
- 4. ARO is the owner of United States Patent No. 6,372,252 (the "'252 patent").
- 5. ART is the holder of several New Drug Applications ("NDAs") under which the United States Food and Drug Administration ("FDA") granted approval to market these guaifenesin-containing pharmaceutical formulations.
- 6. Pursuant to 21 U.S.C. § 355(j), Mutual has filed Abbreviated New Drug Application ("ANDA") No. 78-333 with the FDA, seeking permission to market 600 and 1200 mg generic versions of ART's NDA products. Mutual's ANDA No. 78-333 currently is pending with the FDA and has not yet been approved.
- 7. In Adams Respiratory Operations, Inc. v. Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc., Civil Action No. 2:06-CV-04418-PD, and Adams Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc., Civil Action No. 2:06-CV-05485-PD, Adams has alleged that Mutual infringed certain claims of the '252 patent by submitting ANDA No. 78-333 to the FDA.
- 8. In the Lawsuits, Mutual has asserted several claims, defenses, counts and/or counterclaims, including that the '252 patent is not infringed, invalid and unenforceable, and that Adams has committed exclusionary, anticompetitive and unlawful acts in violation of

the Sherman Act, the Clayton Act and state common law in connection with bringing this action, the '252 patent and NDA No. 21-282.

- 9. Adams and Mutual have reached an agreement to settle the Lawsuits, as set forth in a separate Settlement and License Agreement (the "Settlement Agreement"), which is being executed contemporaneously.
- 10. All claims and counterclaims in the Lawsuits are hereby dismissed without prejudice.
 - 11. Each of the parties shall bear their own costs and attorneys' fees.
- 12. Each of the parties consents to personal jurisdiction in Pennsylvania for purposes of enforcing the Settlement Agreement.

SO STIPULATED:

/s/ Dominick A. Conde

Dominick A. Conde
John D. Carlin
Colleen Tracy
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
(212) 218-2100

Alexander Kerr Lisa M. Salazar McCARTER & ENGLISH, LLP Mellon Bank Center 1735 Market Street, Suite 700 Philadelphia, PA 19103 (215) 979-3800

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Adams Respiratory Operations, Inc.

/s/ James D. Veltrop
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James P. Doyle AXINN, VELTROP & HARKRIDER LLP 1370 Avenue of the Americas New York, NY 10019 Telephone: (212) 728-2200 Facsimile: (212) 728-2201

Howard I. Langer LANGER & GROGAN, P.C. 1600 Market Street, Ste. 2020 Philadelphia, PA 19103

	Telephone: (215) 419-6536 Facsimile: (215) 419-6546
	Attorneys for Defendants Pharmaceutical Holdings Corp; Mutual Pharmaceutical Co., Inc. United Research Laboratories, Inc.
Dated:	Dated:
SO ORDERED:	•
Dated:	
	Honorable Paul S. Diamond

APPENDIX C

FORM OF BULK PRODUCT SUPPLY AGREEMENT

[Supply Agreement form appears on the following pages]

FORM OF BULK PRODUCT SUPPLY AGREEMENT

This BULK PRODUCT SUPPLY AGREEMENT (this "<u>Agreement</u>"), dated as of ______, 20___ (the "<u>Effective Date</u>"), is entered into between **ADAMS RESPIRATORY**OPERATIONS, INC., a Delaware corporation ("<u>Adams</u>"), and MUTUAL

PHARMACEUTICAL COMPANY, INC., a Pennsylvania corporation ("Mutual").

WHEREAS, Mutual and Adams have entered into a Settlement and License Agreement dated as of March ___, 2007 ("<u>License Agreement</u>"), pursuant to which Mutual may elect to obtain quantities of Product(s) from Adams;

WHEREAS, Mutual desires to engage Adams to supply Mutual with Products (defined below) from time to time on the terms and conditions set forth below, and Adams desires to supply such Products to Mutual on such terms and conditions.

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants of the parties set forth in this Agreement, the parties hereto agree as follows:

1. Definitions

Unless this Agreement expressly provides to the contrary, the following terms herein, whether used in the singular or plural, have the respective meanings set forth below:

"Adams Indemnitee" has the meaning set forth in Section 5.5.

"Adams NDA" means New Drug Application No. 21-282, as amended, modified or supplemented from time to time.

"Affiliate" of a Party means any person or entity which controls, is controlled by or is under common control with such Party. As used in this definition, "control" means (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity.

"API" means the active pharmaceutical ingredient(s) of each Product listed on Schedule \underline{A} to this Agreement.

"Applicable Law" means all ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any Authority applicable to the Manufacture, supply and/or use of Products, as amended from time to time, including without limitation cGMP.

"<u>Authority</u>" means any government authority responsible for issuing regulations or granting approvals for the Manufacture, supply and/or use of Products in the Territory, including, without limitation, the FDA.

"Batch" means a specific quantity or lot of a Product that is intended to be of uniform character and quality, within specified limits, and which has been produced during the same cycle of Manufacture as defined by the applicable batch records.

"Batch Documentation" means, with respect to each Batch of Product delivered hereunder, (a) a copy of the executed batch record, (b) a certificate of analysis from Adams for the Batch of Product, and (c) all deviation and investigation reports.

"Calendar Quarter" means, with respect to each Product, each three (3) month period ending on March 31, June 30, September 30 and December 31 during the Term; provided, that the first Calendar Quarter for such Product shall commence on the Mutual Launch Date of such Product and end on the earliest of the next March 31, June 30, September 30 or December 31 thereafter.

"Calendar Year" means, with respect to each Product, the twelve (12) month period commencing on January 1, and each separate successive twelve (12) month period thereafter during the Term; provided, that the first Calendar Year for each Product shall commence on the Mutual Launch Date of such Product and end on the next December 31 thereafter.

"cGMP" means current good manufacturing practices applicable to the Manufacture and supply of Products.

"Confidential Information" has the meaning set forth in Section 6.1.

"<u>Facility</u>" means Adams' facility located at 14801 Sovereign Road, Fort Worth, Texas 76155, at which Adams will Manufacture the Products supplied to Mutual under this Agreement.

"FDA" means the United States Food and Drug Administration and any successor agency having substantially the same functions.

"FDCA" means the United States Food, Drug and Cosmetic Act, 21 U.S.C. §§321 et seq., as amended from time to time.

"Forecast" has the meaning set forth in Section 2.3.

"Inspection Period" has the meaning set forth in Section 2.8.

"Losses" has the meaning set forth in Section 5.4.

"Manufacture" and "Manufacturing" means any steps, processes and activities necessary to produce Product, including without limitation, the manufacturing, processing, bulk packaging and labeling, quality control testing, release and storage of Product.

"Mutual Indemnitee" has the meaning set forth in Section 5.4.

"Mutual Launch Date" means, with respect to a Product manufactured under this Agreement, the first commercial sale of such Product by Mutual and its Affiliates or its single Sublicensee in the Territory.

"Party" means Adams or Mutual, and "Parties" means Adams and Mutual together.

"Product" means each finished dosage form and strength of each pharmaceutical product listed on Schedule A to this Agreement, packaged in bulk.

"Purchase Price" means, with respect to each Product, the purchase price of such Product as defined in Section 3.1.

"Specifications" means, with respect to each Product and its API and excipients, the specifications therefore as approved in the Adams NDA, as they are modified from time to time.

"Sublicensee" means a Third Party to whom Mutual grants a single sublicense under the rights licensed to Mutual under the License Agreement.

"<u>Term</u>" means the period during which this Agreement is in effect as set forth in Section 8.1.

"<u>Territory</u>" means the United States of America, and its territories, commonwealths and possessions, including without limitation, the Commonwealth of Puerto Rico and the District of Columbia.

"Third Party" means any person or entity other than Mutual or Adams or their Affiliates.

2. Manufacture and Supply

2.1 Agreement to Supply. Adams shall Manufacture and supply, or at its sole discretion have Manufactured for supply, to Mutual, and Mutual shall purchase from Adams, each Product in such quantities and at such times as are specified in the purchase orders placed by Mutual pursuant to this Agreement and on the terms and conditions set forth in this Agreement. Adams shall Manufacture each Product pursuant to the applicable Specifications and Applicable Law and shall supply each Product to Mutual in finished form, labeled and packaged in bulk containers. Product shall be white and/or in such other reasonable monocolored configuration mutually agreeable to the Parties, and shall be manufactured using Adams' and its Affiliates' bilayered technology.

- 2.2 <u>API</u>. Adams shall be responsible for obtaining all API, excipients and other materials required for the Manufacture of Product at its own expense. All such API, excipients and other materials shall comply with the Specifications and be compliant with the Adams NDA and Applicable Law, including cGMP, as applicable.
- 2.3 Forecasts. At least ninety (90) days prior to the Mutual Launch Date for a Product, Mutual shall make a good faith estimate of Mutual's projected requirement of such Product for delivery during each of the following six (6) Calendar Quarters. At least sixty (60) days prior to the Mutual Launch Date for a Product, and at least thirty (30) days prior to the first day of each Calendar Quarter for such Product during the Term after such Mutual Launch Date, Mutual shall give Adams Mutual's good faith estimate of Mutual's projected requirements of such Product for delivery during each of the following six (6) Calendar Quarters (each such estimate, a "Forecast"). The first Calendar Quarter of each such Forecast shall be binding in accordance with the terms of Section 2.4(b). The remaining five (5) Calendar Quarters of each such Forecast constitute nonbinding, good faith estimates provided solely to assist Adams in production planning.
- 2.4 <u>Purchase Orders; Binding Orders and Launch Quantities</u>. (a) The purchase and sale of all Products under this Agreement shall be implemented by Mutual's issuance of individual purchase orders to Adams for specific whole lot quantities of Product. Purchase orders shall be placed at least thirty (30) days before the desired delivery date. Purchase orders shall be placed on Mutual's purchase order form, may be transmitted by facsimile and shall be deemed accepted upon Adams' receipt thereof so long as such purchase orders are consistent with the terms and conditions of the Agreement. Such purchase orders shall specify the quantity of Product ordered and the requested delivery date. The means and terms of shipment shall be as set forth in Section 2.5. Any terms that are in addition to or different from the terms of Mutual's purchase order that are contained in any order acceptance or similar document issued by Adams shall be of no force or effect unless expressly accepted by Mutual in writing.
- (b) Mutual shall purchase at least one hundred percent (100%) of the Product quantities in the first Calendar Quarter of each Forecast for each such Product. Each purchase order issued by Mutual constitutes the binding obligation of Adams to Manufacture, sell and deliver to Mutual the quantity of Product by the delivery date specified in such purchase order, and the binding obligation of Mutual to purchase the quantity of Product specified therein; provided, that if Mutual requests any increase in the quantity of any Product in a purchase order in excess of one hundred percent (100%) of such quantities, then Adams shall use commercially reasonable efforts to supply the additional Product quantity. In the event of a conflict between the terms and conditions of this Agreement and any purchase order, the terms and conditions of this Agreement shall prevail.
- 2.5 <u>Shipment</u>. Adams shall ship all Product FCA Facility (Incoterms 2000) to Mutual's facilities in Philadelphia, Pennsylvania or such other destination in the Territory mutually agreed upon by Adams and Mutual. Shipment shall be made by reputable carrier or

another commercially reasonable carrier specified by Mutual in its purchase order. Mutual shall make the necessary arrangement with the shipper and Mutual shall bear shipping costs.

- 2.6 <u>Title: Risk of Loss</u>. Title to, and risk of loss of, the Product shall pass from Adams to Mutual upon delivery to the carrier as set forth in Section 2.5.
- 2.7 <u>Problems with Supply</u>. Adams shall promptly notify Mutual of any circumstances that result or are likely to result in any failure or delay in the supply or delivery of any Product, including without limitation the underlying reasons for such shortage, proposed remedial measures, the date such shortage is expected to end, and the amount of such Product allocated to fill Mutual's Forecast and orders. Adams shall allocate to Mutual an amount of such Product proportionate to Mutual's requirements divided by the total demand for such Product for the ensuing one-year period. In making any such allocation, Adams shall not give any priority to its own requirements or those of its Affiliates.
- 2.8 Product Inspection and Defective Products. (a) All Product received by Mutual shall be subject to inspection and testing by Mutual in accordance with Mutual's quality assurance program within a period of thirty (30) days from date of shipment of such Product ("Inspection Period"). Prior to the expiration of the Inspection Period, Mutual shall notify Adams in writing if the results of any inspection or testing indicate that Product does not conform to the applicable Specifications or the other requirements of this Agreement. Any product not refused by Mutual during the Inspection Period shall be deemed accepted by Mutual. Adams shall have ten (10) days within which to respond to Mutual's notice. Disputes between the parties not resolved during such ten (10) day period shall be resolved by an independent cGMP laboratory in the United States reasonably acceptable to the parties. Such laboratory shall be appointed not later than fifteen (15) days after the expiry of such ten (10) day period. The determination of such laboratory shall be binding on both parties as to Mutual's right to reject or revoke acceptance of the Product, and the fees and expenses of the laboratory shall be borne by the Party whose opinion was rejected.
- (b) If the Parties, by mutual agreement, find, or if the laboratory finds, the Product to be nonconforming, then at Mutual's discretion Adams shall (i) promptly deliver, at Adams' expense, replacement Product that conforms to the requirements of this Agreement, or (ii) refund or credit to Mutual all payments made by Mutual in respect of such non-conforming shipment. Mutual shall return or destroy nonconforming Product at Adams' expense, including without limitation Mutual's reasonable transportation and handling costs. Payment for Product by Mutual shall not be deemed acceptance of such Product; and no payment shall be due until Mutual receives fully conforming Product. If the Parties mutually agree, or if the laboratory finds, the Product to be in compliance with said Specifications and the other terms of the Agreement, Mutual shall pay any unpaid portion of the Purchase Price therefor. Mutual's acceptance of a Batch shall not relieve Adams of its obligations under this Agreement with respect to such Batch and shall not affect Mutual's rights of recovery if any certification or documentation provided by Adams with respect thereto is false or inaccurate.

3. Financial Terms

- 3.1 <u>Purchase Price</u>. The purchase price for each Product is set forth in <u>Schedule B</u> ("<u>Purchase Price</u>"). All references to currency in this Agreement shall be in United States dollars.
- 3.2 <u>Invoices and Payment</u>. Adams shall invoice Mutual for Products supplied to Mutual at any time after delivery of the Product, referencing in each such invoice the purchase order(s) to which the invoice relates, the Purchase Price per unit of Product and quantity of Product shipped. Subject to the terms of Section 2.8(b), Mutual shall pay all undisputed amounts to Adams for Product purchased pursuant to this Agreement in U.S. Dollars within thirty (30) days of the date of invoice or airway bill, whichever is later, by wire transfer to the bank account designated in writing by Adams to Mutual in advance.
- 3.3 Adams and its Affiliates shall keep correct and complete books of accounts and other records containing all information and data which may be necessary to ascertain and verify the Purchase Price payable by Mutual under this Agreement. During the Term and for a period of two (2) years following its termination, Mutual shall have the right from time to time (at Mutual's expense) to have an independent certified public accountant inspect such books and records. Such inspection shall be conducted after reasonable prior notice by Mutual to Adams during Adams' ordinary business hours and shall not be more frequent than once during each Calendar Year. Any such independent certified accountant shall be reasonably acceptable to Adams, shall execute Adams' standard form of confidentiality agreement, and shall be permitted to share with Mutual solely its findings with respect to the accuracy of the Purchase Price invoiced under this Agreement. If such accounting determines that Mutual paid Adams more than the amount properly due in respect of any period, then Adams shall promptly reimburse Mutual such amount, and if the amount overpaid exceeds five percent (5%) of the amount actually due then Adams shall also reimburse Mutual for the costs of such audit.

4. Regulatory Matters

- 4.1 <u>Adams NDA</u>. Adams shall maintain the Adams NDA in good standing, and be responsible for all regulatory decisions and communications with respect to the applicable Product in and for the Territory, including but not limited to adverse event reporting, safety issues, product complaints relating to bulk product, field alerts and product recalls.
- 4.2 <u>Notification of Certain Events</u>. Adams shall notify Mutual promptly upon becoming aware of any: (a) pending or threatened litigation, governmental investigation, proceeding or action involving any Product or the Facility, (b) defective, adulterated or misbranded Product or of any information which may suggest that any Product is or may be defective, adulterated or misbranded, and (c) Product which fails to meet the Specifications, the requirements of the Adams NDA, Applicable Law or cGMP, or any information which may suggest that the Product does not or may not meet the Specifications, the requirements of the

Adams NDA or cGMP. Adams shall promptly investigate and provide Mutual with all reasonable assistance requested by it in connection with adverse experiences and customer complaints relating to Products.

- 4.3 <u>Regulatory Inspections</u>. Adams agrees to notify Mutual promptly of any inspections by the FDA or any other Authority which pertain to or have any quality implications for any Product, or if such inspection impacts Adams' ability to provide Product. Adams shall allow, and shall provide Mutual with any required authorization to allow the FDA, or other Authority, to inspect, audit and review the facilities at which the Product is Manufactured and all procedures, practices, books, records, and documents to the extent requested by the FDA or such Authority.
- 4.4 Access to Facilities. Mutual shall have the right once per Calendar Year, upon two (2) weeks notice to Adams and during normal business hours, to audit for two (2) business days Adams' facilities and records for the Product to ensure that Product is being Manufactured in compliance with the Specifications, the Adams NDA and all Applicable Laws, including without limitation cGMP, and otherwise to ascertain compliance with the terms of this Agreement. During such audits, Adams shall make available to Mutual the appropriate knowledgeable personnel of Adams. Adams shall also make available to Mutual and its duly authorized representatives and agents all books, records and documents that in any way pertain to the Manufacture or quality control, testing and compliance procedures of the Product.
- 4.5 Record Retention. Adams shall retain originals of all Batch Documentation, any and all other records or documentation generated by it in connection with the processing and testing of each Product under the terms of this Agreement, and all records which may be reasonably necessary to assist Mutual in the event of a Product recall or adverse drug event, for the period required by Applicable Law.
- 4.6 Recalls. If any Authority seizes any Product or requests or requires the recall of any such Product, or a Party deems it necessary to initiate a voluntary recall of any such Product for any reason, then the Party receiving notice of such governmental action or initiating such recall, as the case may be, shall notify the other Party immediately of such seizure or recall and the parties shall consult with each other regarding the timely compliance with all Applicable Laws pertaining thereto. If such a recall or removal results from or arises out of the negligence, willful misconduct or breach of this Agreement by Adams, the costs and expenses of such recall or removal, including, without limitation, expenses and other costs or obligations to Third Parties and the cost and expense of notifying customers, shipment and destruction of recalled Product shall be borne by Adams and, at Mutual's discretion, Adams shall promptly replace, at no cost to Mutual, the seized or recalled Product with an equal quantity of complying Product or refund Mutual the full cost of such seized or recalled Product.
- 4.7 <u>Quality Agreement</u>. If Adams or Mutual deems it necessary or desirable, or if required by Applicable Law, the parties agree to enter into a Quality Agreement governing the requirements and respective responsibilities of the parties with respect to Product quality matters.

5. Warranties and Indemnification

- 5.1 <u>Representations and Warranties of Adams</u>. Adams represents and warrants to Mutual that:
- (a) (i) this Agreement is a legal, valid and binding obligation of Adams, enforceable against Adams in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by general principles of equity; (ii) Adams is not subject to any judgment, order, injunction, decree or award of any court, administrative agency or governmental body that would or might interfere with its performance of any of its material obligations hereunder; (iii) Adams has full power and authority to enter into and perform its obligations under this Agreement in accordance with its terms; (iv) it owns and has the legal rights to the Adams NDA; (v) the Manufacturing and supply of Product shall be performed with requisite care, skill and diligence, in accordance with Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified, and (vi) the Manufacturing, importation and supply of Product shall not infringe the intellectual property rights of any Third Party and Adams shall promptly notify Mutual in writing should it become aware of any claims asserting such infringement.
- (b) at the time of delivery to Mutual, each Product Manufactured under this Agreement (i) shall have been Manufactured in accordance with Adams NDA, cGMP and all other Applicable Laws, the Manufacturing process, quality requirements, and Specifications, and (ii) shall not be adulterated or misbranded under the FDCA or other Applicable Laws.
- 5.2 <u>Representations and Warranties of Mutual.</u> Mutual represents and warrants to Adams that:
- (a)(i) this Agreement is a legal, valid and binding obligation of Mutual, enforceable against Mutual in accordance with its terms, except as enforcement may be limited to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by general principles of equity; (ii) Mutual is not subject to any judgment, order, injunction, decree or award of any court, administrative agency or governmental body that would or might interfere with its performance of any of its material obligations hereunder; (iii) Mutual has full power and authority to enter into and perform its obligations under this Agreement in accordance with its terms; (iv) the sale and distribution of Product shall be performed with requisite care, skill and diligence, in accordance with Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified.
- (b) Product purchased under this Agreement shall not be adulterated or misbranded by any act of Mutual under the FDCA or other Applicable Laws.

- 5.3 <u>Disclaimer</u>. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.
- 5.4 <u>Indemnity by Adams</u>. Adams shall indemnify and hold harmless Mutual, its Affiliates and their respective officers, directors, employees and agents (each a "<u>Mutual Indemnitee</u>") from and against any and all losses, damages, liabilities or expenses (including reasonable attorneys fees and other costs of defense) (collectively, "<u>Losses</u>") in connection with any and all actions, suits, claims or demands that may be brought or instituted against any Mutual Indemnitee by any Third Party to the extent such Losses are based on, arising out of, or resulting from, any (a) breach by Adams of its representations, warranties or covenants hereunder, or (b) negligent act or omission or the willful misconduct of any Adams Indemnitees in performing obligations under this Agreement.
- 5.5 <u>Indemnity by Mutual</u>. Mutual shall indemnify and hold harmless Adams, its Affiliates and their respective officers, directors, employees and agents (each an "<u>Adams Indemnitee</u>") from and against any and all Losses in connection with any and all actions, suits, claims or demands that may be brought or instituted against any Adams Indemnitee by any Third Party to the extent such Losses are based on, or arising out of, or resulting from (a) breach by Mutual of its representations, warranties or covenants hereunder, or (b) any negligent act or omission or the wilful misconduct of any Mutual Indemnitees in performing obligations under this Agreement.
- 5.6 <u>Indemnification Procedures</u>. (a) Each Party agrees to notify the other Party within thirty (30) days of receipt of any claims made for which the other Party might be liable under Section 5.4 or 5.5, as the case may be. The indemnifying Party shall have the right, but not the obligation, to defend, negotiate, and settle such claims unless the indemnified Party waives its right to indemnification. The indemnified Party shall be entitled to participate in the defence of such matter and to employ counsel at its expense to assist therein; <u>provided</u>, <u>however</u>, that if the indemnifying Party elects to defend the indemnified Party, the indemnifying Party shall have final decision-making authority regarding all aspects of the defence of any claim. The Party seeking indemnification shall provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party.
- (b) Neither Party shall be responsible or bound by any settlement of any such claim or suit made without its prior written consent; provided, however, that the indemnified Party shall not unreasonably withhold or delay such consent. In the event that a settlement contains an absolute waiver of liability for the indemnified Party, and each Party has acted in compliance with the requirements of Section 5.6(a), then the indemnified Party's consent shall be deemed given. Notwithstanding the foregoing, Adams shall not agree to settle any claim on such terms or conditions as would impair Mutual's ability or right to manufacture, market, sell or otherwise use

Product, or as would impair Adams' ability, right or obligation to perform its obligations hereunder.

6. Confidentiality

- shall keep confidential Information. During the Term and continuing thereafter, each Party shall keep confidential and not disclose to others or use for any purpose, other than as authorized by this Agreement, all "Confidential Information" which was provided to it by the other Party or its Affiliates or their respective employees or representatives pursuant to this Agreement. For purposes of this Agreement, the term "Confidential Information" means any and all know-how, trade secrets, formulae, data, inventions, technology and other information, including manufacturing techniques, processes, trade and financial information, related to the Manufacture, use, sale or marketing of the Product, currently in the possession of, or developed during the Term by, either Adams or Mutual or any of their respective Affiliates. The restrictions of this Section shall not apply to any Confidential Information which (a) is already known to the recipient at the time of disclosure, as reasonably documented by written records; (b) is or later becomes public knowledge through no fault of the recipient; (c) is received from a Third Party having the lawful right to disclose the information; or (d) is independently developed by employees of the recipient without access to the disclosing Party's Confidential Information.
- Permitted Disclosure. A Party may disclose Confidential Information of the other Party to (a) its Affiliates and single Sublicensee, and to its and their directors, employees, consultants, and agents in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use and (b) the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; provided, however, that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure, including upon the disclosing Party's request, seeking confidential treatment of such Confidential Information.
- 6.3 Return of Confidential Information. This Agreement does not constitute the conveyance of ownership with respect to or a license to any Confidential Information, except as otherwise provided in this Agreement. Upon the expiration or termination of this Agreement (in its entirety or with respect to any Product) for any reason, each Party agrees, except as otherwise provided in this Agreement, to return to the other Party all documentation or other tangible evidence or embodiment of Confidential Information belonging to the other Party (and relating to the terminated Product) and not to use same, unless otherwise agreed in writing.
- 6.4 <u>Publicity</u>. Except as consistent with press releases mutually agreed by the Parties, and other information disclosed in this Agreement and the License Agreement, including this Agreement or the License Agreement as provided to the pertinent regulatory authorities such as the Securities and Exchange Commission, no public announcement or other disclosure to Third Parties concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party and

agreement upon the nature, text and timing of such announcement or disclosure; <u>provided</u>, <u>however</u>, either Party shall have the right to make any such public announcement or other disclosure required by applicable law after such Party has provided to the other Party a copy of such announcement or disclosure and a reasonable opportunity to comment thereon. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure.

7. Insurance

Insurance. Throughout the Term and (a) for a period of twenty-four (24) months 7.1 thereafter, or (b) until the date twelve (12) months following the expiry date of the last lot of the Product delivered under this Agreement, whichever is later, each Party shall maintain in full force and effect, at its own cost and expense, (i) product liability insurance (exclusive of the coverage provided by the general liability policy), with a minimum limit per occurrence of \$5,000,000 and an aggregate limit of at least \$5,000,000 and (ii) general liability insurance, including contractual liability insurance, with a minimum of \$5,000,000 combined single limit for bodily injury and property damage per occurrence; in each case naming the other Party and its Affiliates as additional insureds thereon, and providing that the insurer shall give the other Party at least ninety (90) days prior written notice of cancellation, non-renewal or any material change in coverage. Such insurance coverage shall be provided by an insurer or insurers (having a minimum AM Best rating of A or otherwise acceptable to the other Party, in its sole discretion) licensed to do business in the Territory and shall be primary and non-contributing to any liability insurance carried by the other Party. Each Party shall deliver to the other Party, promptly upon request, a certificate of insurance evidencing the foregoing.

8. Term and Termination

- 8.1 <u>Term of Agreement</u>. This Agreement shall become effective on the Effective Date and shall remain in force with respect to each Product unless sooner terminated by mutual consent or pursuant to this Article 8.
- 8.2 <u>Termination for Breach</u>. If either Party at any time breaches any of the material provisions of this Agreement and fails to cure such breach within thirty (30) days after receiving written notice from the non-breaching Party of such breach, then the non-breaching Party may upon written notice to the other Party terminate this Agreement with respect to any Product that is the subject of or adversely affected by such material breach.
- 8.3 <u>Bankruptcy or Insolvency</u>. If either Party becomes bankrupt or insolvent, files for a petition therefor, makes an assignment for the benefit of creditors, or has a receiver appointed for its assets, which appointment shall not be vacated within sixty (60) days after the filing, then the other Party shall be entitled to terminate this Agreement forthwith by written notice to such Party.

- 8.4 <u>Unilateral Termination Right</u>. Mutual may terminate this Agreement with respect to any Product upon one year written notice to Adams.
- 8.5 Survival of Rights. The termination of this Agreement in its entirety or with respect to a Product for any reason shall be without prejudice to, and shall not affect, the right of either Party to recover from the other any and all payments to which either Party may be entitled, or any other rights of either Party, and all such rights of both shall survive any such termination. In addition, any termination of this Agreement in its entirety or with respect to a Product shall not release the parties from liabilities and obligations accrued as of the date thereof. Notwithstanding anything to the contrary that may be contained herein, in the event of the termination or expiration of this Agreement, Sections 4.2, 4.3, the last sentence of 4.4, 4.5, 4.6 and this 8.5 and Articles 5, 6, 7 and 9 shall survive.

9. Miscellaneous

9.1 <u>Notice</u>. All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be (as elected by the Party giving such notice) hand delivered by messenger or courier service, telecommunicated (include additional language), or mailed by registered or certified mail (postage prepaid), return receipt requested, or delivered by overnight delivery service, addressed to:

If to Mutual: Mutual Pharmaceutical Company, Inc.

1100 Orthodox Street Philadelphia, PA 19124 Attention: President

With a copy to:

Mutual Pharmaceutical Company, Inc. 1100 Orthodox Street Philadelphia, PA 19124 Attention: Legal Department

If to Adams: Adams Respiratory Therapeutics, Inc.

4 Mill Ridge Lane Mill Ridge Farm Chester, NJ 07930

Attention: Chief Executive Officer

With a copy to:

Adams Respiratory Therapeutics, Inc. 4 Mill Ridge Lane

Mill Ridge Farm Chester, NJ 07930 Attention: General Counsel

Each such notice shall be deemed delivered (1) on the date delivered if by personal or overnight delivery, and (2) on the date upon which the return receipt is signed or delivery is refused or the notice is designated by the postal authorities as not deliverable, as the case may be, if mailed.

- 9.2 <u>Further Assurances</u>. Each Party agrees to execute and deliver any and all such other and additional instruments and documents and do any and all such other acts and things as may be necessary or expedient to effectuate more fully this Agreement and to carry out the business contemplated by this Agreement.
- 9.3 <u>Force Majeure</u>. The inability of any Party to commence or complete its obligations hereunder by the dates herein required resulting from delays caused by strikes, insurrection, acts of God, war, emergencies, or other causes beyond the Party's reasonable control which shall have been timely communicated to the other Party, shall extend the period for the performance of the obligations for the period equal to the period(s) of any such delays(s) and such Party shall not be liable to the other Party for such delay; provided that such Party shall continue to perform to the extent feasible in view of such *force majeure*.
- 9.4 <u>Assignment; Binding Effect.</u> Neither Party hereto may assign any of its rights or obligations under this Agreement without the prior written consent of the other Party, <u>except</u> to an Affiliate, or in connection with a merger, reorganization, change of control or sale of all or substantially all of the business of such Party to which this Agreement relates. Any purported assignment in violation of the foregoing shall be null and void *ab initio* and of no force or effect. No assignment of this Agreement will relieve the assigning Party from any of its obligations hereunder. In the event of a permitted assignment, this Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns.
- 9.5 <u>Waiver and Amendment</u>. Any representation, warranty, covenant, term or condition of this Agreement which may legally be waived, may be waived, or the time of performance thereof extended, at any time by the Party hereto entitled to the benefit thereof, and any term, condition or covenant (including, without limitation, the period during which any condition is to be satisfied or any obligation performed) may be amended by the Parties hereto at any time. Any such waiver, extension or amendment by a Party shall be evidenced by an instrument in writing executed by an officer of such Party authorized to execute waivers, extensions or amendments. No waiver by any Party, whether express or implied, of its rights under any provision of this Agreement or otherwise shall constitute a waiver of such Party's rights under such provisions at any other time or a waiver of such Party's rights under any other provision of this Agreement. No failure by any Party to take any action against any breach of this Agreement or default by the other Party shall constitute a waiver of the non-breaching

Party's right to enforce any provision of this Agreement or to take action against such breach or default or any subsequent breach or default by such other Party.

- 9.6 Entire Agreement. This Agreement, including the Schedules attached hereto, together with the License Agreement, contains every obligation and understanding between the parties relating to the subject hereof and merges all prior discussions, negotiations and agreements, if any, between them, and none of the parties shall be bound by any conditions, definitions, understandings, warranties or representations other than as expressly provided or referred to herein.
- 9.7 <u>Severability</u>. If any provision of this Agreement is held invalid, illegal or unenforceable for any reason, the Parties shall negotiate in good faith for a substitute provision to continue the intent and purpose of such invalid provision taking into account the intent and purpose of the overall Agreement, and the validity, legality and enforceability of the remaining provisions shall not be in any way impaired thereby.
- 9.8 <u>Section Headings</u>. The section headings in this Agreement are for convenience of reference only and shall not be deemed to affect the interpretation of any provision of this Agreement.
- 9.9 Relationship of Parties. It is expressly agreed that Adams is an independent contractor of Mutual and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither Adams nor Mutual shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.
- 9.10 <u>Remedies</u>. The Parties agree that there is no adequate remedy at law for the damage which either Party might sustain for breach of this Agreement and, accordingly, each Party shall be entitled, as its option, to specific performance, in addition to any other remedy at law or in equity, to enforce the terms hereof
- 9.11 <u>Construction</u>. The Parties agree and acknowledge that this Agreement is the product of both Parties and shall not be construed against either of the Parties other than in accordance with its terms. The Parties acknowledge that each has been advised by counsel during the course of negotiation of this Agreement and, therefore, that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted.
- 9.12 <u>Governing Law</u>. This Agreement and any dispute arising out of or related to this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York, without giving effect to conflicts of law principles that would dictate the application of the law of another jurisdiction. The application of the 1980 United Nations

Convention on Contracts for the International Sale of Goods is expressly excluded from this Agreement.

- 9.13 Jurisdiction: Venue. Any suit, action or proceeding against any Party with respect to this Agreement or any judgment entered by any court in respect of this Agreement shall be brought in state or federal courts located in the Eastern District of Pennsylvania, and the parties hereto accept the exclusive jurisdiction of such court for the purpose of any such suit, action or proceeding. In addition, the parties irrevocably waive, to the fullest extent permitted by law, any objection which they may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement, or any judgment entered by any court in respect hereof brought in the Eastern District of Pennsylvania and further irrevocably waive any claim that any suit, action or proceeding brought in the Eastern District of Pennsylvania was brought in an inconvenient forum.
- 9.14 <u>Third Party Beneficiaries</u>. No person other than the Parties hereto and their respective Affiliates, successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any legal or equitable rights or benefits to enforce any provision of this Agreement.
- 9.15 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, and execution by each of the Parties of anyone of such counterparts will constitute due execution of this Agreement. Each such counterpart hereof shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement by their authorized representatives effective as of the date first above written.

Ву:
Name:
Title: President
ADAMS RESPIRATORY OPERATIONS, INC.
By:
Name:
Title:

MUTUAL PHARMACEUTICAL COMPANY, INC.

SCHEDULE A

PRODUCTS

Product Description (i.e., finished dosage form(s) and strength(s))	
	_
	_
	_

SCHEDULE B

PURCHASE PRICE

The Purchase Price for each Product in each Calendar Year shall equal the Fully Allocated Cost Basis for such Product in such Calendar Year, where "Fully Allocated Cost Basis" means, with respect to a particular Product in any period, (a) to the extent that such Product is manufactured by Adams, the direct costs to Adams of manufacturing the units of finished Product sold to Mutual during such period as calculated in accordance with generally accepted accounting principles in the United States consistently applied by Adams, including (i) to the extent not already included in clause (ii) below, the direct acquisition cost of all raw materials and components, including the active pharmaceutical ingredient used therein, (ii) the direct costs, including direct labor and materials, of producing, packaging and labeling such Product, (iii) the direct costs for transportation, insurance and/or storage consistent with the delivery terms of such Product and any applicable sales taxes, (iv) a reasonable allocation of manufacturing overhead costs reasonably attributable to such Product (but excluding corporate administrative overhead, depreciation and/or costs associated with excess capacity), and (v) any royalty payments made by Adams to Third Parties in consideration for a license to manufacture such Product; and (b) to the extent that such Adams Guaifenesin Product is manufactured by a Third Party contract manufacturer, the actual price paid by Adams to such Third Party for the production, packaging and labeling of the units of such Adams Guaifenesin Product sold in such period.

Thirty (30) days prior to the Mutual Launch Date for a Product and thirty (30) days prior to each Calendar Year thereafter during the Term, Adams shall provide Mutual with the Purchase Price of such Product as calculated above, and such Purchase Price shall apply to such Product for the subsequent Calendar Year, with the exception that Adams may adjust the Purchase Price once during the Calendar Year upon thirty (30) days prior written notice to Mutual.